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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/548,465	04/13/2000	Robert F. Bencini	15916-261	7431

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EXAMINER

SIRMONS, KEVIN C

ART UNIT PAPER NUMBER

3763

DATE MAILED: 01/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 09/548,465	Applicant(s) BENCINI ET AL.	
	Examiner Kevin C. Sirmons	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 November 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-21, 23-26, 43-54, 64 and 65 is/are pending in the application.  
     4a) Of the above claim(s) 3, 6-10 and 12-16 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 25, 47, 48, 50 and 51, 53, 54 is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4, 5, 11, 17-21, 23, 24, 26, 43-46, 49, 52 and 64 is/are rejected.
- 7) ☒ Claim(s) 65 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 4-5, 11 are 17-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to claim 1, it is unclear and the examiner has no idea what is meant by "the distal portion of the elongated body defining a proximal end and being more flexible than the proximal portion." Is applicant implying that the distal end portion is more flexible than the proximal end portion?

As to claim 18, it is unclear what applicant is attempting to claim. The claim appears to be incomplete.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 4, 5, 11, 17-21, 23, 24, 26, 43-46 and 49, 52 and 64 are rejected under 35 U.S.C. 102(b) as being anticipated by Webster, Jr. U.S. Pat. No. 5,431,168.

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Webster discloses an elongate body (10), the distal portion of the elongate body defining a proximal end and being more flexible than the proximal portion (col. 3); a steering wire (36); a stiffening member, entirely located inward of the outer surface of the elongate body, and defining a proximal end that is substantially adjacent to the proximal end of the elongated body distal portion (48 and/or 38); a handle (fig. 8 and see handle throughout specification); as to claim 2, (stiffening member lumen (22) and stiffening member (62); as to claim 4, (38 and/or 48); as to claim 5, (38 and/or 48); as to claim 11, (38 and/or 48)); as to claim 17, (fig. 1); as to claim 18, (see above rejections); as to claim 19, (fig. 1); as to claim 20 (see above rejections and anchoring member (31)); as to claim 21, (portion of the weld are made from stainless steel, therefore, a portion of the anchoring member is substantially radiopaque); as to claim 22, (figs. 1 and 4); as to claim 23, (fig. 4 and (51));

as to claim 24, an elongate body (10); a steering wire having a distal portion (36); an anchoring member (31); a stiffening member (48 and/or 38); an anti-tear ((49 and 15) note: anti-tear device has no structure and is not connected to anything)); as to claim 26, (col. 6 addresses diagnostic element and therapeutic element); as to claim 43, (fig. 1 and 4); as to claim 44, (19); as to claim 46, see distal end of (figs. 1 and 4); as to claim 45, (19); as to claim 49, an elongate body, (10); a steering wire (36); a stiffening member (19); an anti-tear device (21, 38 and 51); as to claim 64, an elongate body (10); a stiffening member (38); anti-tear means (49) and a steering wire (36).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 52 is rejected under 35 U.S.C. 103(a) as being unpatentable over Webster.

Webster discloses an apparatus substantially as claimed except for a substantially c-shaped anti-tear device. As to claim 52, an elongate body (10); a stiffening member (19) a c-shaped member (38) with a slot (interior of 38) and a steering wire (36). Webster's tubular member is cylindrical, which the examiner regards as substantially c-shaped. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to vary the shape of the component, since such a modification would have involved a mere change in a shape of a component. A change in shape is generally recognized as being within the level of ordinary skill in the art *In re Dailey*, 357 F. 2d 669, 149 USPQ 47 (CCPA 1966);

***Response to Arguments***

Applicant's arguments with respect to claims 1, 4, 5, 11, 17-19, 26, 24, 43-45, 52 and 64 have been considered but are moot in view of the new ground(s) of rejection.

As to claims 20, 21 and 23, and in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the

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features upon which applicant relies (i.e., the description of the anchoring member from the specification) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Additionally, the lumen is within the wall of the catheter between the inner surfaces and the outer surface (fig. 2). The anchoring member is clearly anchored within the lumen, which is within the wall. Therefore, the rejection is maintained.

As to claim 49, one of ordinary skill in the art can clearly see that the rejection of claim 49 does not refer back to previous rejections. Noticeably, Webster discloses an elongate body (10); a steering wire (36); a stiffening member (19) and an anti-tear device (21, 38 and 51) as recited in the claims. Claim 49 has very little structure; therefore, Webster can easily read on the limitations set forth in claim 49.

### ***Allowable Subject Matter***

Claim 65 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim 25, 47, 48, 50, 51, 53 and 54 are allowable over the prior art of record.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin C. Sirmons whose telephone number is 571-272-4965. The examiner can normally be reached on Monday-Friday 6:30-4:00 ALT FRI.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kevin C. Sirmons  
Primary Examiner  
Art Unit 3763

1/8/05  
*Kevin C. Sirmons*